



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, with sufficient postage, addressed to: Commissioner for Patents, Washington, D.C. 20231, on

May 20, 2002

Date of Deposit

Jonathan P. Taylor, Ph.D., Reg. No. 48,338

Name of Applicant, Assignee or
Registered Representative

Jonathan P. Taylor
Signature

5/20/02

Date of Signature

Our Case No.: 10466/286

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jeffrey Cleland et al.

Serial No.: 10/080,502

Filing Date: February 22, 2002

For: ERODIBLE POLYMERS FOR
INJECTION

Examiner: To be assigned

Group Art Unit No.: 1614

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed below and on the attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

The references now cited are the following:

US PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	NAME
4,297,344	10/27/1981	Schwinn et al.
4,938,763	7/3/1990	Dunn et al.
4,975,271	12/4/1990	Dunn et al.
5,019,400	5/28/1991	Gombotz et al.
5,077,049	12/31/1991	Dunn et al.
5,096,885	3/17/1992	Pearlman et al.
5,133,981	7/28/1992	Harkrader et al.
5,242,910	9/7/1993	Damanj
5,278,201	1/11/1994	Dunn et al.
5,278,202	1/11/1994	Dunn et al.
5,324,519	6/28/1994	Dunn et al.
5,324,520	6/28/1994	Dunn et al.
5,340,849	8/23/1994	Dunn et al.
5,368,859	11/29/1994	Dunn et al.
5,487,897	1/30/1996	Polson et al.
5,556,905	9/17/1996	Frappier et al.
5,589,167	12/31/1996	Cleland et al.
5,591,713	1/7/1997	Igari et al.
5,599,552	2/4/1997	Dunn et al.
5,651,986	7/29/1997	Brem et al.
5,665,394	9/9/1997	Igari et al.
5,747,058	5/5/1998	Tipton et al.
5,780,044	7/14/1998	Yewey et al.
5,783,205	7/21/1998	Berggren et al.
5,912,015	6/15/1999	Bernstein et al.
5,945,115	8/31/1999	Dunn et al.
5,972,370	10/26/1999	Eckenhoff et al.
6,039,977	3/21/2000	Venkatraman et al.
6,051,259	4/18/2000	Johnson et al.
6,066,619	5/23/2000	Stevenson et al.
6,080,429	6/27/2000	Cleland et al.
6,087,324	7/11/2000	Igari et al.
6,110,503	8/29/2000	Rickey et al.
6,113,943	9/5/2000	Okada et al.
6,113,947	9/5/2000	Cleland et al.
6,120,789	9/19/2000	Dunn

DOCUMENT NUMBER	DATE	NAME
6,124,261	9/26/2000	Stevenson et al.
6,130,200	10/10/2000	Brodbeck et al.
6,143,314	11/7/2000	Chandrashekar et al.
6,146,662	11/14/2000	Jao et al.
6,165,508	12/26/2000	Tracy et al.
6,174,547 B1	1/16/2001	Dong et al.
6,190,700 B1	2/20/2001	Okada et al.
6,191,107 B1	2/20/2001	Yamagata et al.
6,197,350 B1	3/6/2001	Yamagata et al.

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY
EP 0 216 485 A1	4/01/1987	Europe
WO 89/03671	5/5/1989	PCT
WO 92/17200	10/15/1992	PCT
EP 0 484 387 B1	1/19/1994	Europe
MX 173182 A	7/2/1994	Mexico
WO 98/27962 A2	7/2/1998	PCT
WO 98/27963 A2	7/2/1998	PCT
WO 00/78335 A1	12/28/2000	PCT

OTHER REFERENCES

Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations", <i>Pharmaceutical Research</i> , Vol. 8, No. 3 (1991) 285-291.
Gray et al., "Cloning of human tumor necrosis factor (TNF) receptor cDNA and expression of recombinant soluble TNF-binding protein", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 87 (1990) 7380-7384.
Johnson et al., "A month-long effect from a single injection of microencapsulated human growth hormone", <i>Nature Medicine</i> , Vol. 2, No. 7 (1996) 795-799.
Kita et al., "Contribution of the Surface Free Energy Perturbation to Protein-Solvent Interactions", <i>Biochemistry</i> , Vol. 33 (1994) 15178-15189.
Kohno et al., "A second tumor necrosis factor receptor gene product can shed a naturally occurring tumor necrosis factor inhibitor", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 87 (1990) 8331-8335.
Lai et al., "Metal and RNA Binding Properties of the hdm2 RING Finger Domain", <i>Biochemistry</i> , Vol. 37, No. 48 (1998) 17005-17015.

Lin et al., "On the role of surface tension in the stabilization of globular proteins", <i>Protein Science</i> , Vol. 5 (1996) 372-381.
Maa et al., "Spray-Drying of Air-Liquid Interface Sensitive Recombinant Human Growth Hormone", <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 2 (1998) 152-159.
Sackett et al., "Multivalent Cations Depress Ligand Binding to Cell-Associated Insulin-Like Growth Factor Binding Protein-5 on Human Glioblastoma Cells", <i>Endocrinology</i> , Vol. 139, No. 4 (1998) 1943-1951.
Smith et al., "A Novel Parenteral Delivery System", <i>Pharmaceutical Research</i> , PDD 7270, Vol. 13, No. 3 (1996) 1 page.
Timasheff, S.N., "The Control of Protein Stability and Association by Weak Interactions with Water: How Do Solvents Affect These Processes?" <i>Annu. Rev. Biophys. Biomol. Struct.</i> , Vol. 22 (1993) 67-97.
Timasheff, S.N., "Control of Protein Stability and Reactions by Weakly Interacting Cosolvents: The Simplicity of the Complicated", <i>Advances in Protein Chemistry</i> , Vol. 51 (1998) 355-432.
Timasheff, S.N., "Solvent Stabilization of Protein Structure", <i>Methods in Molecular Biology</i> , Vol. 40 (1995) 253-269.
Xie et al., "The thermodynamic mechanism of protein stabilization by trehalose", <i>Biophysical Chemistry</i> , Vol. 64 (1997) 25-43.
Yang et al., "Effect of Zinc Binding and Precipitation on Structures of Recombinant Human Growth Hormone and Nerve Growth Factor", <i>Journal of Pharmaceutical Sciences</i> , Vol. 89, No. 11 (2000) 1480-1485.

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).


This Information Disclosure Statement is being filed prior to the receipt of the first Official Action reflecting an examination on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these material, the Commissioner is hereby authorized to deduct said fees from Brinks

Hofer Gilson & Lione Deposit Account No. 23-1925. A duplicate copy of this document is enclosed.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

5/20/02



Jonathan P. Taylor, Ph.D.
Registration No. 48,338
Agent for Applicants

BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, IL 60610
Tel. (312) 321-4200
Fax (312) 321-4299



FORM PTO-1449	SERIAL NO. 10/080,502	CASE NO. 10466/286
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE February 22, 2002	GROUP ART UNIT 1614
(use several sheets if necessary)		APPLICANT(S): Jeffrey Cleland et al.

REFERENCE DESIGNATION		U.S. PATENT DOCUMENTS				
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A1	4,297,344	10/27/1981	Schwinn et al.		
	A2	4,938,763	7/3/1990	Dunn et al.		
	A3	4,975,271	12/4/1990	Dunn et al.		
	A4	5,019,400	5/28/1991	Gombotz et al.		
	A5	5,077,049	12/31/1991	Dunn et al.		
	A6	5,096,885	3/17/1992	Pearlman et al.		
	A7	5,133,981	7/28/1992	Harkrader et al.		
	A8	5,242,910	9/7/1993	Damanj		
	A9	5,278,201	1/11/1994	Dunn et al.		
	A10	5,278,202	1/11/1994	Dunn et al.		
	A11	5,324,519	6/28/1994	Dunn et al.		
	A12	5,324,520	6/28/1994	Dunn et al.		
	A13	5,340,849	8/23/1994	Dunn et al.		
	A14	5,368,859	11/29/1994	Dunn et al.		
	A15	5,487,897	1/30/1996	Polson et al.		
	A16	5,556,905	9/17/1996	Frappier et al.		
	A17	5,589,167	12/31/1996	Cleland et al.		
	A18	5,591,713	1/7/1997	Igari et al.		
	A19	5,599,552	2/4/1997	Dunn et al.		
	A20	5,651,986	7/29/1997	Brem et al.		
	A21	5,665,394	9/9/1997	Igari et al.		
	A22	5,747,058	5/5/1998	Tipton et al.		
	A23	5,780,044	7/14/1998	Yewey et al.		
	A24	5,783,205	7/21/1998	Berggren et al.		
	A25	5,912,015	6/15/1999	Bernstein et al.		
	A26	5,945,115	8/31/1999	Dunn et al.		
	A27	5,972,370	10/26/1999	Eckenhoff et al.		
	A28	6,039,977	3/21/2000	Venkatraman et al.		
	A29	6,051,259	4/18/2000	Johnson et al.		
	A30	6,066,619	5/23/2000	Stevenson et al.		

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449	SERIAL NO. 10/080,502	CASE NO. 10466/286
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE February 22, 2002	GROUP ART UNIT 1614
(use several sheets if necessary)		APPLICANT(S): Jeffrey Cleland et al.

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

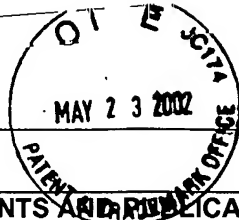
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A31	6,080,429	6/27/2000	Cleland et al.		
	A32	6,087,324	7/11/2000	Igari et al.		
	A33	6,110,503	8/29/2000	Rickey et al.		
	A34	6,113,943	9/5/2000	Okada et al.		
	A35	6,113,947	9/5/2000	Cleland et al.		
	A36	6,120,789	9/19/2000	Dunn		
	A37	6,124,261	9/26/2000	Stevenson et al.		
	A38	6,130,200	10/10/2000	Brodbeck et al.		
	A39	6,143,314	11/7/2000	Chandrashekar et al.		
	A40	6,146,662	11/14/2000	Jao et al.		
	A41	6,165,508	12/26/2000	Tracy et al.		
	A42	6,174,547 B1	1/16/2001	Dong et al.		
	A43	6,190,700 B1	2/20/2001	Okada et al.		
	A44	6,191,107 B1	2/20/2001	Yamagata et al.		
	A45	6,197,350 B1	3/6/2001	Yamagata et al.		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES	NO
	A46	EP 0 216 485 A1	4/01/1987	Europe			
	A47	WO 89/03671	5/5/1989	PCT		Abstract only	
	A48	WO 92/17200	10/15/1992	PCT			
	A49	EP 0 484 387 B1	1/19/1994	Europe			
	A50	MX 173182 A	7/2/1994	Mexico			
	A51	WO 98/27962 A2	7/2/1998	PCT			
	A52	WO 98/27963 A2	7/2/1998	PCT			
	A53	WO 00/78335 A1	12/28/2000	PCT			

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449	SERIAL NO. 10/080,502	CASE NO. 10466/286
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)	FILING DATE February 22, 2002	GROUP ART UNIT 1614
APPLICANT(S): Jeffrey Cleland et al.		

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
	A54	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations", <i>Pharmaceutical Research</i> , Vol. 8, No. 3 (1991) 285-291.
	A55	Gray et al., "Cloning of human tumor necrosis factor (TNF) receptor cDNA and expression of recombinant soluble TNF-binding protein", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 87 (1990) 7380-7384.
	A56	Johnson et al., "A month-long effect from a single injection of microencapsulated human growth hormone", <i>Nature Medicine</i> , Vol. 2, No. 7 (1996) 795-799.
	A57	Kita et al., "Contribution of the Surface Free Energy Perturbation to Protein-Solvent Interactions", <i>Biochemistry</i> , Vol. 33 (1994) 15178-15189.
	A58	Kohno et al., "A second tumor necrosis factor receptor gene product can shed a naturally occurring tumor necrosis factor inhibitor", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 87 (1990) 8331-8335.
	A59	Lai et al., "Metal and RNA Binding Properties of the hdm2 RING Finger Domain", <i>Biochemistry</i> , Vol. 37, No. 48 (1998) 17005-17015.
	A60	Lin et al., "On the role of surface tension in the stabilization of globular proteins", <i>Protein Science</i> , Vol. 5 (1996) 372-381.
	A61	Maa et al., "Spray-Drying of Air-Liquid Interface Sensitive Recombinant Human Growth Hormone", <i>Journal of Pharmaceutical Sciences</i> , Vol. 87, No. 2 (1998) 152-159.
	A62	Sackett et al., "Multivalent Cations Depress Ligand Binding to Cell-Associated Insulin-Like Growth Factor Binding Protein-5 on Human Glioblastoma Cells", <i>Endocrinology</i> , Vol. 139, No. 4 (1998) 1943-1951.
	A63	Smith et al., "A Novel Parenteral Delivery System", <i>Pharmaceutical Research</i> , PDD 7270, Vol. 13, No. 3 (1996) 1 page.
	A64	Timasheff, S.N., "The Control of Protein Stability and Association by Weak Interactions with Water: How Do Solvents Affect These Processes?" <i>Annu. Rev. Biophys. Biomol. Struct.</i> , Vol. 22 (1993) 67-97.
	A65	Timasheff, S.N., "Control of Protein Stability and Reactions by Weakly Interacting Cosolvents: The Simplicity of the Complicated", <i>Advances in Protein Chemistry</i> , Vol. 51 (1998) 355-432.
	A66	Timasheff, S.N., "Solvent Stabilization of Protein Structure", <i>Methods in Molecular Biology</i> , Vol. 40 (1995) 253-269.

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449	SERIAL NO. 10/080,502	CASE NO. 10466/286
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE February 22, 2002	GROUP ART UNIT 1614
(use several sheets if necessary)		APPLICANT(S): Jeffrey Cleland et al.

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
	A67	Xie et al., "The thermodynamic mechanism of protein stabilization by trehalose", <i>Biophysical Chemistry</i> , Vol. 64 (1997) 25-43.
	A68	Yang et al., "Effect of Zinc Binding and Precipitation on Structures of Recombinant Human Growth Hormone and Nerve Growth Factor", <i>Journal of Pharmaceutical Sciences</i> , Vol. 89, No. 11 (2000) 1480-1485.

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.